# **Guidelines for Post-Study Research Animal Disposition**

## <u>Introduction/Background</u>:

The goal of this guideline is to outline the stipulations and considerations applicable to the transfer of NIH-owned animals following their research use to a private individual or organization; protect the transferred animal's welfare; prevent the transfer of zoonotic infections; and close the transferring institution's financial liability towards the care of the transferred animal.

All NIH Institutes and Centers (ICs) using research animals should develop an Animal Care and Use Committee (ACUC)-approved research animal disposition policy which outlines the procedures associated with transferring ownership of a research animal following the completion of their use in research to a person or organization for non-research use. The IC animal disposition policy should address the roles and responsibilities of key personnel managing the transfer in compliance with the clearance procedures outlined in the Deputy Director for Intramural Research's (DDIR's) Disposition of Animals Memorandum dated June 4, 2014<sup>1</sup>.

NIH's Office of Laboratory Animal Welfare (OLAW) has issued recommendations (Frequently Asked Question F.11) on the disposition of laboratory animals upon their research use completion in the following statements excerpts:

- "OLAW supports the safety and protection of animals and reminds institutions that their policies must clarify the disposition of animals acquired for research once the research has ended, which may include adoption.
- The PHS will not assume legal or financial responsibility for any adoption program or any matters arising from or related to the adoption of research animals.
- The institution should ensure that its policy meets pertinent state and local laws and regulations for the transfer of animal ownership and is encouraged to coordinate with local animal shelters.
- For purposes of property standards under the uniform administrative requirements for HHS grant awards, animals purchased for research purposes are considered to be supplies. Generally, the title to supplies vests with the grant recipient upon acquisition (45 CFR 75.321)."<sup>2</sup>

As the PHS Policy applies to animal research conducted by PHS agencies, such as NIH, OLAW's recommendations are also relevant to the disposition of NIH IRP animals. The Code of Federal Regulations recordkeeping regulations offer institutions the option of developing and implementing a policy for transfer of ownership<sup>3</sup>. (<u>Title 9: Code of Federal Regulations, Chapter 1, Subchapter A: Animal Welfare</u>). In 2014 the NIH DDIR authorized the transfer of ownership of NIH laboratory animals from the Federal Government to a private recipient with the following stipulations:

• The approval authority for the transfer of ownership of a research animal resides with the Scientific Director or their designee.

- The IC must complete a transfer of ownership agreement that identifies the terms of the transfer, health of the animal at the time of the transfer and relinquishes NIH of responsibility for the animal once the transfer has occurred.
- The transfer of ownership agreement should be developed and reviewed by the NIH Office of General Counsel (OGC).

#### General:

- Animals placed in private homes or non-profit organizations for fostering or retirement, must not be sold, released into the wild, used for food, or used as working animals following transfer from the NIH IRP.
- Collaborations with outside placement groups should only occur after careful review of the group's history, mission statement, reputation, and animal adoption experience.
- The following sections of this guideline are intended to provide considerations to assist IRP programs with development of their own policies and procedures regarding animal disposition and placement after study completion. Policies must be approved by the IC ACUC, with subsequent review a minimum of triennially.

#### **Animal Transfer Eligibility Determination:**

Any animal considered or proposed for transfer should be evaluated by the Attending Veterinarian or designee and the Principal Investigator or other investigator knowledgeable on the history of the animal including but not limited to the following items to determine its suitability for transfer:

- research use history (exposure to recombinant DNA, infectious agents, test articles, etc.)
- liability risk
- biosecurity issues
- species
- the animal must be of no current monetary value to NIH or another federal entity; that the costs of continued care of the animal exceed the amount of a potential sale of the animal; or that the original cost of the animal was less than \$500.00<sup>4</sup>.
- health status
- temperament

Diagnostic testing, appropriate vaccinations, and surgical sterilization may be performed prior to transfer as deemed necessary by the Attending Veterinarian.

#### **Animal Receiving Agents or Institutions:**

Potential adopters and/or fosters of research animals should be interviewed to determine if they possess the following minimum requirements:

- Familiarity with the general behavior and care requirements for the animal species being considered for transfer,
- Ability to physically and properly care for the animal,
- Sufficient resources required for lifelong animal care,
- Proper space for the animal to exercise, and

• Absence of zoning restrictions, HOA by-laws or covenants preventing animal ownership.

#### **Animal Transfer Records:**

At the time of ownership transfer, an entry will be made in the animal's medical record that the animal was transferred. A Transfer of Animal Ownership Agreement will be signed and copied; one copy to the Recipient (adopter) and one copy of the transfer agreement to be included in the animal's permanent record maintained at NIH. Per the 2014 DDIR memo, the transfer agreement must include the following:

- identifies the terms of the transfer,
- confirms good health of the animal at the time of the transfer, and
- relinquishes NIH of responsibility for the animal once the transfer has occurred.

## **Animal Transfer Procedure:**

On the day of the transfer, the individual receiving the animal will bring an appropriate animal transport crate to transfer the animal from the NIH to its new home. The NIH does not provide transport crates for the adoption or transfer of animals.

Once the animal leaves the NIH facility, and is in the possession of its new owner, the NIH will no longer be responsible for the animal's future veterinary or behavioral care. Transfer of the animal's ownership releases NIH of all liabilities demands, damages, expenses and losses arising out of the Recipient's care. All records of adoption will be maintained by the IC for three (3) years per the NIH Records Management Schedule.<sup>5</sup>

#### **Example Transfer of Animal Ownership Agreement:**

Please see Attachment 1 on page 5 of this document.

#### **Example IC Animal Disposition Policy:**

The NIH Office of Research Services, Division of Veterinary Resources (DVR) has a policy for the transfer of DVR-owned research animals that have completed their assigned study (ORS-DVR Animal Adoption/Retirement Policy--OAM Policy Number P10001). The PI/IC that owns the animal will be responsible for any incurred expenses for housing, examinations, and other evaluations during the adoption process. No animals may be transferred to a DVR holding protocol during the adoption process.

#### References:

- 1. Deputy Director for Intramural Research. Disposition of Laboratory Animals. June 5, 2014. <a href="https://oacu.oir.nih.gov/system/files/media/file/2021-02/memo\_disposition.pdf">https://oacu.oir.nih.gov/system/files/media/file/2021-02/memo\_disposition.pdf</a>
- 2. Frequently Asked Questions: PHS policy on Humane Care and Use of Laboratory Animals: https://olaw.nih.gov/faqs#/guidance/faqs?anchor=question50374
- 3. <u>Title 9: Code of Federal Regulations, Chapter 1, Subchapter A, Part 2, Subpart C, Part 2.35: Recordkeeping Requirements</u>. Washington, D.C.: Office of Federal Register.
- 4. <u>Title 41: Code of Federal Regulations, Chapter 102: Subchapter B, Part 102-36:</u>
  <u>Disposition of Excess Personal Property.</u> Washington, D.C.: Office of Federal Registrar.
- NIH Records Management Schedule and Storage:

https://oma.od.nih.gov/DMS/Pages/Records-Management-Schedule.aspx

6. Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). April 2019.

Approved – 04/27/2022

## **Attachment 1: Sample Transfer Agreement**

Note: This is a sample template, and therefore, the format shown is not required. If the below form is modified, review by the NIH Office of General Counsel is strongly recommended.

#### TRANSFER OF ANIMAL OWNERSHIP AGREEMENT

This Transfer of Animal Ownership Agreement has been adopted for use by the National Institutes of Health to transfer the legal ownership of an animal(s) from the Federal Government to a private recipient pursuant to 41 C.F.R. 102. 36.305-330.

Provider [name of the NIH program transferring the animal(s)]:

**Recipient** [name of individual receiving the animal(s)]:

The Provider agrees to transfer the following animal(s) to the Recipient [describe the animal(s)]:

#### TERMS OF AGREEMENT

- Recipient agrees to use the animal(s) solely for non-commercial purposes and will not sell or otherwise transfer the animal.
- Provider has attached to this Agreement documents concerning the animal's relevant medical history and current health status.
- Recipient agrees that it will adhere to all applicable national standards for humane care and use of the animal(s) and accepts full responsibility for the animal (s) including any and all future costs related to the animal'(s') care, housing, treatment, behaviors and well-being.
- In accepting the animal(s), Recipient accepts full ownership, custody, and control of the animal(s) except that to the extent the Government has any patent, invention or any other intellectual property rights in the animal(s), the Government retains these rights. Additionally, to the extent that any party other than the Government has any patent, invention or other intellectual property rights in the animal(s), these rights are not transferred to the Recipient.
- The animal(s) is transferred to the Recipient with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Unless prohibited by law from doing so, Recipient agrees to hold the United States Government harmless and to indemnify the Government from all liabilities, demands, damages, expenses, and losses arising out of Recipient's care, use, or treatment of the animal(s).
- Recipient agrees not to claim, infer, or imply Governmental endorsement of the Recipient, the institution, or personnel.
- The undersigned Recipient expressly certifies and affirms that the statements made herein are truthful and accurate.
- The undersigned Provider expressly certifies and affirms that he or she is authorized to sign this Agreement on behalf of their institution, the animal is of no current monetary value or functional use to NIH or to other entities of the Government, that costs of continued care and handling of the animal exceed the costs of any potential sale of the animal or that the original cost to acquire the animal was less than \$500.00 and that the statements made herein are truthful and accurate.

This animal transfer agreement shall be construed in accordance with Federal law as applied by the United States Court of Appeals for the District of Columbia.

Date Recipient Signature	
Recipient's Name, Title, Mailing Address	
Date (IC/APD) Director (Approving Official) Signature	
(IC/APD) Director (Approving Official) Name, Title	